DEPARTMENT OF HEALTH AND HUMAN SERVICES Public Health Service

Food & Drug Administration
12420 Parklawn Drive
Rockville MD 20857
RM 3109

James D. Smith, Chief of Criminal Appeals
Office of the Attorney General
2115 State Capitol
Lincoln, NE 68509
Tel: 402-499-1489

Re: Cook v. FDA (formerly Beaty v. FDA), CA No. 1:11-cv-00289 (RJL)

Dear Mr. Smith:

On March 27, 2012, the District Court for the District of Columbia entered its decision and order in Cook v. FDA in favor of plaintiffs, death row inmates, and against the U.S. Food and Drug Administration (FDA). As part of the relief provided to the plaintiffs, the Court ordered FDA to "immediately notify any and all state correctional departments which it has reason to believe are still in possession of any foreign manufactured thiopental that the use of such drug is prohibited by law and that, that thiopental must be returned immediately to the FDA." *See* attached Order.

Subsequent to receiving the Court's order, FDA contacted your office and was informed that the Nebraska Department of Correctional Services is in possession of foreign-manufactured thiopental.

In light of the foregoing, FDA asks that you contact me at your earliest convenience to make arrangements for the return to FDA of any foreign-manufactured thiopental in your possession.

I can be contacted at (301) 796-6673 or by e-mail at Domenic.Veneziano@fda.hhs.gov.

Sincerely,

Domenic J. Veneziano,
Director, Division of Import Operations and Policy

Enclosure: Order, Cook v. FDA, CA No. 1:11-cv-00289 (RJL) (D.D.C. Mar. 27, 2012)
cc: Jon Bruning, Attorney General

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

DONALD EDWARD BEATY, *et al.*,	)	
	)	
Plaintiffs,	)	
	)	
v.	)	**Civil Case No. 11-289 (RJL)**
	)	
FOOD AND DRUG ADMINISTRATION,	)	
	)	
and	)	
	)	
U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES,	)	
	)	
and	)	
	)	
KATHLEEN SEBELIUS, in her official capacity as Secretary of the U.S. Department of Health and Human Services,	)	
	)	
and	)	
	)	
MARGARET A. HAMBURG, M.D., in her official capacity as Commissioner of Food and Drugs,	)	
	)	
Defendants.	)	

ORDER
(March 27, 2012)

For the reasons set forth in the Memorandum Opinion entered this 27th day of March, 2012, it is hereby

ORDERED that plaintiffs' Motion for Summary Judgment and Declaratory Relief on Counts I and III [#12] is **GRANTED**; and it is further

ORDERED that the defendants' Motion to Dismiss and/or for Summary Judgment [#13] is **DENIED**; and it is further

DECLARED, pursuant to 28 U.S.C. § 2201(a), that

1. the foreign manufactured thiopental (or "thiopental") imported by the importing States (e.g. Arizona, California, South Carolina, Georgia, and Tennessee) is a misbranded drug and an unapproved new drug within the meaning of the FDCA; and

2. as such, this thiopental cannot lawfully be introduced or delivered for introduction into interstate commerce or lawfully be imported into the United States; and

3. defendants' recent actions allowing such thiopental to enter the United States were each contrary to law, arbitrary, capricious, and an abuse of discretion under the APA; and, in particular,

4. defendants' January 4, 2011 announcement that they will allow future shipments of such thiopental to enter the United States is contrary to law, arbitrary, capricious, and an abuse of discretion under the APA; accordingly

IT IS HEREBY ORDERED that the FDA:

1. immediately notify any and all state correctional departments which it has reason to believe are still in possession of any foreign manufactured thiopental that the use of such drug is prohibited by law and that, that thiopental must be returned immediately to the FDA; and

2. be permanently enjoined from permitting the entry of, or releasing any future shipments of, foreign manufactured thiopental into interstate commerce; and

IT IS FURTHER ORDERED that the parties are hereby directed to meet and confer to determine whether further litigation is necessary, or proper, with respect to the remaining count in this Complaint.

SO ORDERED.

RICHARD J. LEON
United States District Judge

DEPARTM
HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration
Rockville MD 20857

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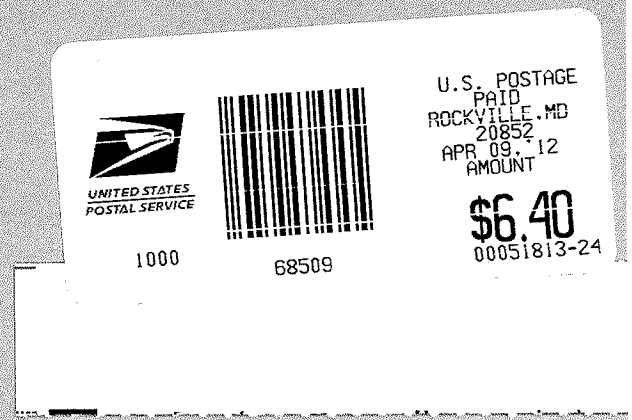

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STATE OF NEBRASKA
DEPARTMENT OF JUSTICE

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